

REMARKS

Claims 1-47 are currently pending in the present application, with claims 14, 15, 19-28 and 31-47 having been provisionally withdrawn by the Examiner as being directed to a non-elected species. Thus, claims 1-13, 16-18 and 29-30 are currently under consideration pending the allowance of a generic claim. Claim 1 is an independent claim drawn to an extended or controlled release product with the remaining claims under consideration depending therefrom and adding further limitations. Claim 5 has been amended to remove duplications found therein. Applicants thank the Examiner for pointing out this typographic error in the claim.

The drawings are objected to for the reasons set forth in the Notice of Draftperson's Patent Drawing Review. 1-13, 16, 17, 29 and 30 stand rejected under 35 U.S.C. §103(a) as being obvious over Krishnamurthy (U.S. Patent No. 5,508,043).

These remarks are presented in the expectation that they place this application in condition for allowance. Accordingly, entry of the remarks is respectfully requested.

Objection to the Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84.

Applicants submit herewith two sheets of formal drawings in which the objections based on the Notice of Draftperson's Patent Drawing Review have been corrected. Applicants respectfully request entry of the drawings into the application and reconsideration and withdrawal of the objection to the drawings.

Rejection of Claims 1-13, 16, 17, 29 and 30

under 35 U.S.C 103(a)

Claims 1-13, 16, 17, 29 and 30 stand rejected under 35 U.S.C. §103(a) as being obvious over Krishnamurthy (U.S. Patent No. 5,508,043) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

Applicant respectfully submits that the reference of record, the Krishnamurthy patent, does not teach or suggest Applicants' inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this reference that would lead one of ordinary skill in the art to modify the reference to arrive at the subject of the amended claims with any expectation of success at the time the invention was made.

The U.S. Supreme Court in Graham v. John Deere Co., 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

A. The present inventive subject matter

Independent claim 1 is drawn to an extended or controlled release encapsulated product, comprising at least one active ingredient, at least one erodible polymer, and at least one lubricating material. The product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters.

The remaining claims depend from claim 1, or from a claim that depends from claim 1, and therefore necessarily contain all of the limitations found therein.

B. The prior art

The Krishnamurthy patent (U.S. Patent No. 5,508,043) discloses a controlled release of a therapeutically active agent from a controlled release matrix of sodium alginate and a calcium salt. When the composition is to be administered as a suppository, the matrix is combined with a therapeutically active agent and a suppository base. When the composition is to be administered orally, the matrix further includes a higher aliphatic alcohol.

C. The differences between the claimed subject matter

and the prior art

The differences between applicant's inventive subject matter

and the cited reference is apparent from their independent and distinct disclosures and claims. Claim 1 (and the claims which depend therefrom) claim an extended or controlled release encapsulated product, comprising at least one active ingredient, at least one erodible polymer, and at least one lubricating material. The product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters. Claims 3 and 5 provide lists of water soluble and water insoluble erodible polymers which can be used in claim 1. As can be seen from these claims, a large number of materials may be used as the erodible polymer.

The Krishnamurthy patent, on the other hand, is directed **only to the combination of sodium alginate and a calcium salt**. Further, the calcium salt is essential to the disclosure of Krishnamurthy in order to cross-link with the alginate when in solutions. The present claims do not call for an edible polymer with a calcium salt. In fact, the patent's disclosure is very limited in scope, and Applicants respectfully submit that one of ordinary skill in the art would not be led to the present claims by following the disclosure in the Krishnamurthy patent.

This is especially true since the Krishnamurthy patent is also silent with respect to the size of the caplet being claimed. As is detailed in the present specification, the size of the caplet aids

in providing a controlled or extended release product with high levels of active ingredients and helps produce a product with uniform active ingredient content throughout. The size of the caplet also helps withstand mechanical pressure both in the processing of the caplet and in the chewing of the product in the mouth so that the active ingredients are released in the stomach of the consumer. Thus, the size of the caplet is an important feature of the present inventive subject matter.

The Krishnamurthy patent is silent with respect to these features and there is no motivation or teaching within the patent to modify it in an attempt to achieve the present subject matter. As is indicated above, the patent is concerned **only** with sodium alginate **and a calcium salt** which is essential to cross-link with the alginate when exposed to solutions (col. 5, lines. 24-26). Thus, the Krishnamurthy patent is very narrow in scope, as the inventor focused only on the combination of sodium alginate and a calcium salt. There is nothing to lead one of ordinary skill in the art to modify the teachings of Krishnamurthy and expand the coverage thereof.

Since the teachings of the Krishnamurthy patent are deficient in disclosing each claimed limitation, Applicants respectfully submit that the Examiner has failed to prove a *prima facie* case of obviousness, which requires that the prior art references teach or

suggest all of the claimed limitations. It is clear that the prior art reference cited by the Examiner fail to accomplish this and there is no motivation to modify the reference, and thus the claims are not obvious over the references. Applicant, therefore, respectfully request reconsideration and withdrawal of the alternative obviousness rejection.

Accordingly, Applicant respectfully submits that the present inventive subject matter, as claimed in the rejected claims, is not rendered obvious by the Krishnamurthy patent. Applicant request reconsideration and withdrawal of these rejections.

CONCLUSION

In view of the foregoing, Applicant respectfully submits that the present claims are patentable over the prior art of record in this case and requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Attorney Docket No. 24222-X2
Serial No. 09/982,092

Respectfully submitted,

NATH & ASSOCIATES

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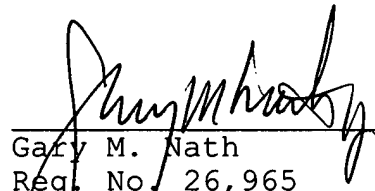
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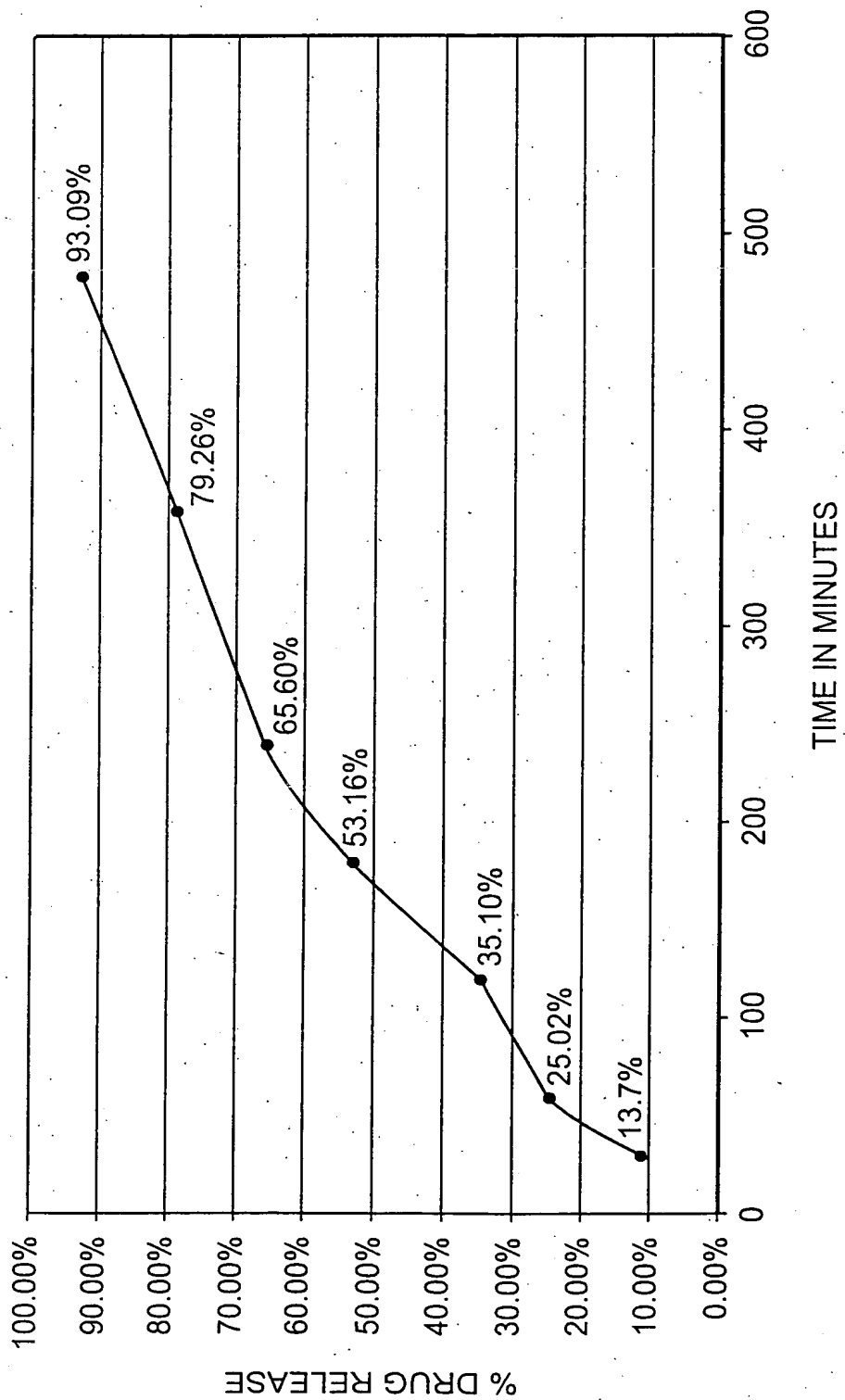


FIG. 1

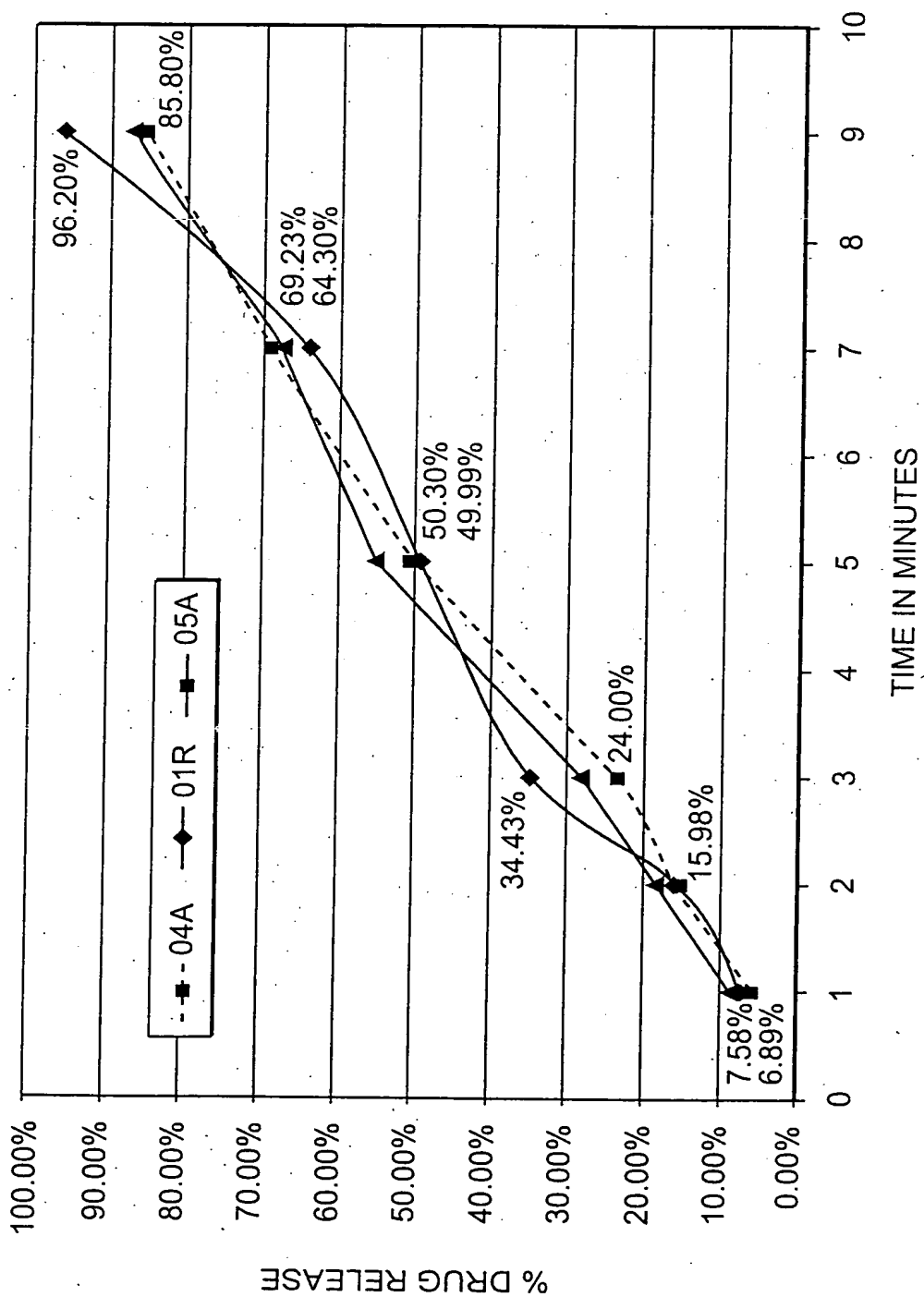


FIG. 2